

Letter. Inasmuch as no new matter is embodied by the proposed amendments, entry thereof is respectfully requested.

The Examiner's objection to the title is overcome by the above amendment. The Examiner's objection to the numbering of the claims is also overcome by the above amendment. Accordingly, withdrawal of these grounds of objection is respectfully requested.

The rejection of the claims under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention, is believed to be obviated by the above amendment, whereby each of the specific objections set forth in paragraphs 5-(i)-(v) have been addressed. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 USC 102(b) over Martindale in view of Panoz as being completely anticipated is respectfully traversed insofar as this ground of rejection is directed to the claims as presently amended. Martindale discloses that "glyceryl trinitrate is a peripheral and coronary vasodilator---used in the management of angina pectoris, myocardial infarction and heart failure---(and) to control blood pressure during surgery". At page 876 the reference discloses:

"---studies of topical therapy (for impotence) have investigated glyceryl trinitrate, applied either as ointment or as a transdermal delivery system to the penis---"

The reference also discloses that "Proprietary Preparations" of glyceryl trinitrate include Nitro-Bid. Panoz is said to disclose in the paragraph bridging cols. 3 and 4 that Nitro-Bid contains lactose, lanolin and petrolatum. It is the Examiner's position, therefore, that Martindale anticipates the claimed invention.

This position contains a number of fatal flaws. First, Martindale does not disclose that the preparations "studied" for the treatment of impotence contain glyceryl trinitrate AND lanolin. The reference merely states that glyceryl trinitrate has been investigated and that it

has been applied as an ointment or as a transdermal delivery system. In the left column of page 876 where this disclosure appears there is no mention whatsoever of the presence of lanolin in any such "ointment" or "transdermal delivery system". Nor is the Examiner's position helped by the fact that, in the right column of page 876 it is disclosed that *one* proprietary preparation is "Nitro-Bid" and that the secondary reference discloses that "Nitro-Bid" contains lanolin. The inescapable fact remains that Martindale does not disclose that "Nitro-Bid" has been used to treat impotence. Moreover, the list of Proprietary Preparations listed at pages 876-877 that includes "Nitro-Bid" is extensive, containing over a hundred different preparations. The Examiner has selected the one such preparation that suits the need of the stated ground of rejection because it contains lanolin. Where is the justification for extrapolating this disclosure into a teaching of the use of "Nitro-Bid" to treat impotence topically? It is respectfully submitted that 35 USC 102 requires certainty of disclosure in a reference to justify a finding of anticipation of novelty. Martindale contains no such certainty since it does not disclose the combination of lanolin and glyceryl trinitrate to topically treat impotence.

And, it is uncontroverted by the Examiner that lanolin is a critical ingredient in the claimed composition. As such, it is incumbent on the Examiner to point to a disclosure in the combination of references that anticipates the use of lanolin in the treatment of impotence. The most that the Examiner is able to do, given the references relied upon, is to state that certain investigators have "studied" the effect of glyceryl trinitrate on impotence. The Examiner is not free to state that the prior art shows the investigation of the use of lanolin, either alone or in combination with glyceryl trinitrate or any other agent to treat impotence.

Secondly, there is no disclosure that the "Nitro-Bid" disclosed in Martindale has the same composition as the "Nitro-Bid" disclosed by Panoz. It is well established that tradenames are not necessarily exclusive to a particular composition. Rather, it is common for

a single tradename to be used in conjunction with a variety of materials having widely varying compositions. See MPEP § 608.01(v). Accordingly, unless the Examiner can establish that the tradename, “Nitro-Bid”, as used by Martindale in 1996, describes the same composition as that described by Panoz as “Nitro-Bid” in 1989, the rejection is fatally flawed.

Thirdly, it is uncontroverted by the Examiner that the claims define “effective amounts” of lanolin and glyceryl trinitrate to treat erectile dysfunction. The reference to Martindale is woefully deficient in describing such effective amounts. As noted above, the reference does not disclose the use of lanolin to treat impotence, much less an “effective amount” for such treatment. Moreover, the reference is silent as to the “effective amount” of glyceryl trinitrate to use. Indeed, the reference is equivocal at best in informing those skilled in the art as to whether glyceryl trinitrate is effective at all in treating impotence. Thus, note the disclosure in the left column of page 876:

“---Laboratory and clinical results suggest that such treatment can produce erections in some subjects, although as with injection therapy response rates vary. However, the incidence of headache is high and patients using ointment must wear a condom to protect their partner from the effects---” (emphasis added).

It is apparent that the reference only “suggests” that the treatment with glyceryl trinitrate (alone, i.e., in the absence of lanolin) may be effective in “some cases” and that side effects occur with a “high rate of incidence”. This can hardly be construed as an anticipation of claims that specify effective amounts of glyceryl trinitrate and lanolin for the treatment of erectile dysfunction.

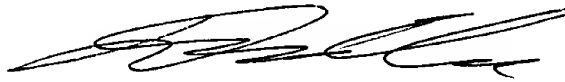
Accordingly, sine the Examiner has not established certainty of disclosure of the claimed invention in the stated combination of references, withdrawal of this ground of rejection is respectfully requested.

The prior art cited by the Examiner but not relied upon has been carefully reviewed. These references will not be discussed in detail. Suffice it to state that none of the references, either alone or in combination, disclose or suggest the claimed invention

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

MILES & STOCKBRIDGE

A handwritten signature in black ink, appearing to read 'Dennis P. Clarke', with a stylized, flowing script.

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